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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,726

08/04/2003

Lee Weng

THRSP0004-0002

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08/01/2006

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EXAMINER

JUNG, WILLIAM C

ART UNIT

PAPER NUMBER

3768

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,726

Applicant(s)

WENG ET AL.

Examiner

William Jung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed June 15, 2006 in regards to claims 10-14 have been fully considered but they are not persuasive.

After further consideration of the applicant's argument on claim 10, examiner respectfully disagrees. Examiner would like to point out that even though the exact reduction of blood flow is not specifically stated by Vaezy et al '867, the reference anticipate such limitation in col. 6, lines 42-45 where the HIFU enables to cause cauterization of tissue at the treatment site for arresting bleeding, preventing bleeding, or cause tissue necrosis, i.e. reducing blood flow.

In regard to claims 11-14 and prior art Chapelon et al '526, examiner would like clarify that although regions outside the focal point of the HIFU is not specifically stated, the region surrounding the focal region of HIFU is heated incidentally since the transmission path of the HIFU does cross the surrounding region. Therefore, examiner maintains the previous office action dated December 165, 2005 and repeated below.

2. Applicant's arguments with respect to claims 15-17 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by *Vaezy et al* '867 (US 6,425,867).

Vaezy et al.'867 teach a method of ultrasonically cutting off the blood supply to a uterine fibroid, comprising the following steps of: a) providing an ultrasonic transducer configured to emit focused high intensity ultrasound energy (see col. 16, lines 19-26; referring to use of high intensity focused ultrasound (HIFU)), b) pre-selecting one or more tissue treatment sites located on the uterine fibroid whereby necrosing the tissues at the one or more tissue treatment site will decrease the blood supply to the uterine fibroid (see col. 16, lines 19-20; referring to treatment of fibroid and col. 16, lines 50-58; referring to necrosing tissue at a plurality of selected locations by causing lesions to the blood vessels).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11, 13, and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over *Vaezy et al* '867 in view of *Chapelon et al* '526(US 5,601,526).

Vaezy et al '867 teach an efficient heating method using high intensity ultrasound energy comprising the following steps: providing an ultrasonic transducer configured to emit focused high intensity ultrasound energy (see col. 16, lines 19-26; referring to use of high intensity focused ultrasound (HIFU)); and determining a tissue treatment zone (an indicated in Figure 6,

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and col. 16, lines 50-58, there is a treatment zone of one or more 112a lesion areas). Vaezy et al '867 do not teach energizing the ultrasound transducer to cause pre-focal heating at the tissue treatment zone and re-energizing the ultrasound transducer to cause necrosis at the tissue treatment zone. In the same field of endeavor, Chapelon et al '526 teach energizing the ultrasound transducer to cause pre-focal heating at the tissue treatment zone and re-energizing the ultrasound transducer to cause necrosis at the tissue treatment zone (see col. 7, lines 17-55 and col. 10, lines 35-63; referring to pre-heating of the area of interest with thermal waves and subsequent treatment at the focal region with focal cavitation waves in order to necrose the tissue).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have modified Vaezy et al '867 and incorporated the teachings of Chapelon et al '526 in the treatment of fibroids because as taught by Chapelon et al '526 this lowers the cavitation threshold providing a more effective treatment at a localized area of interest by limiting the treatment duration and avoiding spreading of the heat (see col. 5, lines 59-65 and col. 10, lines 35-43).

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Vaezy et al* in view of *Chapelon et al* '526 as applied to claim 11 above, and further in view of *Ribault et al* (US 6,488,639).

Vaezy et al '867 in view of Chapelon et al '526 teach all the steps as enumerated above except for the explicit recitation that pre-focal heating of the tissues causes temperature of the tissue to increase to about 50 degrees C. Ribault et al '639 teach that hyperthermia or heating of

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the tissues other than HIFU is performed at about 45 degrees C, which is about 50 degrees C as disclosed by the current invention (see col. 1, lines 17-30).

Therefore, it would have been obvious to one skilled in the art at the time that the invention was made that the hyperthermia temperature is about 50 degrees C as expressly stated by Ribault et al.'639.

8. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Vaezy et al* '867.

Vaezy et al '867 substantially disclose all claimed features in claims 15-17. Vaezy et al.'867 teach a method of ultrasonically cutting off the blood supply to a uterine fibroid, comprising the following steps of: a) providing an ultrasonic transducer configured to emit focused high intensity ultrasound energy (see col. 16, lines 19-26; referring to use of high intensity focused ultrasound (HIFU)), b) pre-selecting one or more tissue treatment sites located on the uterine fibroid whereby necrosing the tissues at the one or more tissue treatment site will decrease the blood supply to the uterine fibroid (see col. 16, lines 19-20; referring to treatment of fibroid and col. 16, lines 50-58; referring to necrosing tissue at a plurality of selected locations by causing lesions to the blood vessels). However, Vaezy et al '867 do not disclose that the HIFU being applied in angles around the circumference of the uterine fibroid. This particular method is obviated by the Vaezy et al '867's HIFU transmission being emitted in beam in circular path (shown in figure 11) so that the uterine fibroid would be covered in angles around circumference depending on the placement of the probe.

Conclusion

9. This is a request for continuation of applicant's earlier Application No. 10/633,726. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

WJ

July 23, 2006


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